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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,897	11/28/2000	Gustave Bergnes	CYTOP009C5	1088

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/724,897

Applicant(s)

BERGNES ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-28-00
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31, 50, 51, and 56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31, 50, 51, and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,4,5,7,9
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's preliminary amendment of 11-28-00 has been entered. Accordingly, claims 1-30, 32-49, 52-55, and 57-59 are now cancelled. Pending claims are 31, 50, 51, and 56.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 31, 50, 51, and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 31 recites variables R_3 , R_3' , R_3'' , R_{15} which do not bear any relationship to the claimed quinazolinone. Said variables relate to the deleted formulae, and thus, need to be deleted as well. Also, the proviso seems unnecessary.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Scope of enablement:** Claims 31, 50, 51, and 56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of the claimed

quinazolinone compounds, does not reasonably provide enablement for the use of said compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The quantity of experimentation necessary;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The breadth of the claims;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986).

From the specification, it appears that the claimed quinazolinone derivatives do not have a therapeutic use associated with them. Bioassays were done for compounds having $-N(R_4)-C(=O)-R_3$ as a substituent, which have been deleted from the instant claims. Thus, with the guidance provided, one skilled in the art would have to carry out undue experimentation to find out if the claimed compounds can inhibit mitotic kinesin KSP, and at what dosage. The state of the art (as evident by references used in the following 102 and 103 rejections) does not relate the claimed compounds to inhibitors of mitotic kinesin KSP, but rather to HIV-1 inhibitors or

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AMPA-receptor antagonists. Thus, given the unpredictable nature of the art, and the vast number of compounds claimed herein, undue experimentation is inevitable for one to figure out which of the claimed compounds can inhibit mitotic kinesin KSP, and how to administer such compounds.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 31, 50, 51, and 56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31, 50, 51, and 56 of copending Application No. 09/ 699,047. Although the conflicting claims are not identical, they are not patentably distinct from each other because compounds of application 09/699,047 embrace the claimed compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by the following references:

- a. **Kazhevnikov et. al.** (CA 78:16128u): The disclosed compound of formula I having R as NH₂ and R₁ as hydrogen is embraced by the claimed formula having the following substituents:

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- i. R_1 represents an aryl group;
 - ii. R_2 , R_2' , R_4 , R_5 , R_6 , R_7 , and R_8 – each represents hydrogen.
- b. **Debnath et. al.** (J. Med. Chem., 1999, Vol. 42, pp. 3203-3209): On page 3205, compound ADS-J14 is embraced by the claimed formula with the following substituents:
- iii. R_1 represents an alkylaryl group;
 - iv. Either R_2 or R_2' represents a lower alkyl group, and the other represents a hydrogen;
 - v. R_4 stands for substituted aryl;
 - vi. R_5 , R_6 , R_7 , and R_8 – each represents hydrogen.
- c. **Chenard et. al.** (EP 884,310 or EP 900,568): Compounds in Examples 8, 10, and 12 of EP'310 are embraced by the claimed formula with the following substituents:
- vii. R_1 represents either a substituted aryl or heteroaryl group;
 - viii. R_2 , R_2' , – each represents hydrogen.
 - ix. any one of R_5 , R_6 , R_7 , and R_8 represents a halogen, while the others stand for hydrogen.
 - x. R_4 is a substituted aryl group.
5. Claim 31 is rejected under 35 U.S.C. 102(e) as being anticipated by the following references:

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d. **Chenard et. al.** (US 6,136,812): Several compounds on columns 27 and 28 of US'812 (e.g., compounds on lines 38, 40, and 50 of column 28) are embraced by the claimed formula with the following substituents:

- ix. R_1 represents either a substituted aryl or heteroaryl group;
- x. $R_2, R_2', -$ each represents hydrogen.
- xi. any one of R_5, R_6, R_7 , and R_8 represents a halogen, while the others stand for hydrogen.
- xii. R_4 is a substituted aryl group.

Thus, at the time of the invention, one skilled in the art would have known how to make compounds as claimed herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Chenard et. al.** (EP'310). Besides the species that anticipate the claimed formula, Chenard et. al. also provides a generic formula I which allows for combination of substituents that read on other compounds in claims 31 and 50, particularly, those having R₁ and R₄ as substituted phenyl groups. The disclosed compounds have different utility from those claimed herein. However, regarding the compounds alone, one of the ordinary skill in the art still would have been motivated to select the claimed compounds because one would have expected them to be useful in treating neurodegenerative, psychotropic disorders. Moreover, with respect to genus-species situations, the issue of patentability has also been decided by the court in *In re Susi*, 440 F 2d. 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 874 F 2d. 804, 10 USPQ 2d. 1843, 1846 (Fed. Cir. 1989). Thus at the time of the invention, it would have been obvious for one skilled in the art to make and use compounds according to the teaching of Chenard et. al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Tamthom N. Truong
Examiner
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March 20, 2002